Appeal No. 16-2179

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,
Plaintiffs-Appellants,

v.

HOSPIRA, INC.,
Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in Case No. 1:15-cv-00839-RGA, Judge Richard G. Andrews

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OPPOSITION TO HOSPIRA, INC.'S MOTION TO DISMISS APPEAL FOR LACK OF JURISDICTION

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July 18, 2016

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Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") respond to Defendant-Appellee Hospira Inc.'s ("Hospira") Motion to Dismiss Amgen's Appeal for Lack of Jurisdiction as follows:

I. INTRODUCTION

This appeal raises an important issue relating to the rights of a Reference Product Sponsor ("RPS") under the Biologics Price Competition and Innovation Act ("BPCIA") to get manufacturing information from a biosimilar applicant in order to identify and enforce its patents before the commercial marketing of the biosimilar product. Amgen has patents potentially infringed by Hospira's cell-culture process. Although Hospira provided some information about its biosimilar product pursuant to 42 U.S.C. § 262(*l*)(2)(A) ("paragraph (2)(A)"), it withheld the information that Amgen needs to evaluate whether Hospira is infringing its cell-culture patents and include an infringement complaint on such patents in the litigation. Hospira refused to produce such information before and after the filing of this lawsuit, and the district court denied Amgen's motion to compel production. Amgen seeks relief on appeal because this Court's decision in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), while holding that the disclosure provision of paragraph (2)(A) is not mandatory (even though the statute uses the word "shall"), stated that such withheld information would be available through discovery once litigation commenced.

Under the BPCIA, a biosimilar applicant is required to provide to an RPS "information that describes the process or processes used to manufacture the biological product that is the subject" of the applicant's abbreviated biosimilar application. § 262(*l*)(2)(A). In *Amgen*, the Court held that a sponsor's sole and exclusive remedy for an applicant's violation of the paragraph (2)(A) disclosure requirement is to file an infringement suit and "access the required information through discovery." 794 F.3d at 1356-57.

In this case, Hospira refused to disclose its cell-culture manufacturing information during the pre-litigation BPCIA exchange and again refused to produce this information in discovery once Amgen filed a patent infringement action under the BPCIA. Amgen asked the district court to order Hospira to produce the information. The district court denied Amgen's request, finding that *Amgen v. Sandoz* is "not on point." (Johnson Decl. Ex. 1 at 39:24-40:2.) Accordingly, although this appeal arises from the district court's denial of a discovery motion, that ruling was tantamount to denying Amgen its sole remedy under paragraph (2)(A).

Amgen respectfully submits that this case presents an important issue in the new regime of litigation under the BPCIA. If Hospira's actions are upheld, then the purposes of the BPCIA will unravel as biosimilar applicants follow the path blazed by Hospira, surgically carving out information from disclosure and remaining

steadfast in opposition to discovery to evade detection of process patent infringement. As this issue firmly meets the requirements of the collateral order doctrine, this Court has jurisdiction over this appeal and Hospira's motion to dismiss should be denied.

II. PROCEDURAL BACKGROUND

A. Amgen's complaint

Amgen initiated this patent infringement lawsuit under the BPCIA on September 18, 2015, and filed its Amended Complaint on November 6, 2015. (Labbé Decl. Ex. A.) Amgen's Amended Complaint includes three counts of patent infringement regarding two Amgen patents and one declaratory judgment count seeking to enforce the 180-day notice of commercial marketing requirement under 42 U.S.C. § 262(*l*)(8)(A). *See Amgen Inc. v. Apotex Inc.*, Appeal No. 2016-1308, slip op. at 4 (Fed. Cir. July 5, 2016) (holding that "the commercial-marketing provision is mandatory and enforceable by injunction").

In its original complaint, Amgen also included a count directed to Hospira's failure to produce complete manufacturing information under paragraph (2)(A). When Amgen filed the original complaint, this Court's decision in *Amgen v. Sandoz* (in which this Court found that the BPCIA does not grant "a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A)," 794 F.3d at 1356), was the subject of a pending petition for en banc

rehearing. After this Court denied en banc review,[1] Amgen filed its Amended Complaint maintaining its factual allegations detailing Hospira's failure to comply with paragraph (2)(A), but omitting the separate count alleging a violation of the statute. In its Amended Complaint, Amgen plainly stated its intention to rely upon this Court's ruling in *Amgen v. Sandoz* to remedy Hospira's non-compliance with paragraph 2(A) (Labbé Decl. Ex. A ¶¶ 12, 44-53) as provided for by this Court: after a sponsor brings an infringement suit under the BPCIA, "it can access the required [manufacturing] information [under paragraph (2)(A)] through discovery." *Amgen*, 794 F.3d at 1356. Amgen provided notice in the Amended Complaint that, if appropriate, it intended to "seek to assert additional patents following eventual receipt of Hospira's manufacturing information to be produced in discovery." (Labbé Decl. Ex. A ¶ 52.)

B. Hospira's refusal to produce required information under paragraph (2)(A)

In March 2015, Hospira produced to Amgen its abbreviated Biologics License Application ("aBLA") for its proposed EPOGEN® biosimilar product. Hospira did not produce, however, any manufacturing information beyond the information contained in its aBLA. After reviewing Hospira's aBLA and finding that it did not contain complete information regarding the composition of the cell-

[1] *Amgen Inc. v. Sandoz Inc.*, Appeal No. 2015-1499, Order Denying Petitions for Rehearing En Banc, Dkt. No. 162 (Fed. Cir. Oct. 16, 2015).

culture medium Hospira uses to manufacture its product, Amgen repeatedly requested, via three letters, that Hospira provide this information because it relates to "the process or processes used to manufacture the biological product that is the subject" of Hospira's aBLA, information that is required to be provided under § 262(*l*)(2)(A). (Labbé Decl. Exs. B, C, D.) Hospira refused to provide the information. (Labbé Decl. Exs. E, F.) Amgen informed Hospira that without this specific manufacturing information, Amgen could not determine whether 42 U.S.C. § 262(*l*)(3)(A) allowed Amgen to include its cell-culture patents on its § 262(*l*)(3)(A) patent list. (Labbé Decl. Ex. C.)

After filing this case, Amgen served discovery requests on Hospira seeking discovery of the composition of the cell-culture medium used in Hospira's manufacturing process. Hospira again refused to provide the information.

C. The district court's ruling

On May 2, 2016, Amgen filed a letter motion seeking an order compelling Hospira to produce the complete manufacturing information regarding the composition of its cell-culture medium that it had refused to provide during both the BPCIA information-exchange process and in response to Amgen's discovery requests in this lawsuit. (Labbé Decl. Ex. G.) On May 4, 2016, the district court held oral argument regarding Amgen's request. The district court issued rulings on both a "narrower ground" and a "broader ground." On the narrower ground, the

district court ordered Hospira to produce the information to Amgen but only if Hospira continued to contest infringement of the element of one of the claims of the patents that Amgen did include in its complaint that requires cells to be cultured "under suitable nutrient conditions." (Johnson Decl. Ex. 1 at 40:15-19.) As Hospira explains in its Motion, Hospira then informed Amgen that it would not contest that its process meets that claim limitation in order to avoid producing the information. (Hospira Mot. at 4 n.2.)

The district court also considered the broader issue of whether Hospira must produce in discovery information regarding the composition of its cell-culture medium to remedy its non-compliance with paragraph (2)(A) in accordance with this Court's decision in *Amgen v. Sandoz*, 794 F.3d at 1356. On the broader basis, the district court denied Amgen's request: "I don't think the *Amgen v. Sandoz* Federal Circuit case is really on point for—not only—it would be controlling, obviously, if it were on point, but it's not on point. I don't think that really impacts this at all." (Johnson Decl. Ex. 1 at 39:24-40:2.)

D. Amgen's appeal

Amgen filed its notice of appeal on June 3, 2016, within thirty days following the district court's May 4, 2016 ruling. On June 7, the Court docketed this appeal.

III. ARGUMENT

A. Amgen's appeal falls within a narrow exception to the final judgment rule

The collateral order doctrine is an exception to the final judgment rule that provides appellate jurisdiction over certain collateral orders that "[1] conclusively determine the disputed question, [2] resolve an important issue completely separate from the merits of the action, and [3] [are] effectively unreviewable on appeal from a final judgment." *Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1220 (Fed. Cir. 2013).

Since the Supreme Court first articulated the collateral order doctrine in *Cohen v. Beneficial Industrial Loan Corp.*, 337 U.S. 541 (1949), it has applied the doctrine to permit appeals of a variety of orders, from those denying qualified immunity, *Mitchell v. Forsyth*, 472 U.S. 511 (1985), to those denying Westfall Act certification and substitution, *Osborn v. Haley*, 549 U.S. 225, 238-39 (2007), and in forma pauperis status, *Roberts v. United States Dist. Court*, 339 U.S. 844 (1950).

1. The district court's order conclusively resolved the issue on appeal

Hospira does not dispute that the district court's ruling conclusively resolved that Hospira need not produce the manufacturing information it failed to disclose to Amgen as part of its paragraph 2(A) disclosure. (Hospira Mot. at 12 n.4.)

2. The district court's order decided an important issue separate from the merits: that discovery in a 35 U.S.C. § 271(e)(2)(C) patent infringement action is unavailable to remedy an applicant's non-compliance with paragraph (2)(A)

The collateral order doctrine provides appellate jurisdiction over "important issue[s] completely separate from the merits of the action." *Nixon v. Fitzgerald*, 457 U.S. 731, 742 (1982) (quoting *Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 547 (1949)). Hospira contends that the paragraph (2)(A) issue is not separate from the merits of this action because it would require this Court to "necessarily have to consider Amgen's claims against Hospira." (Hospira's Mot. at 16.) But given Hospira's concession as to the process claim that is at issue in the case, the manufacturing information that Amgen seeks under paragraph (2)(A) is *not* relevant to the patent infringement claims to be tried.

In accordance with this Court's holding in *Amgen v. Sandoz*, Amgen's remedy for Hospira's failure to comply with the disclosure provision of paragraph 2(A) is to file a patent infringement action under 35 U.S.C. § 271(e)(2)(C) and seek the manufacturing information in discovery. The district court determined that Amgen was not entitled to this remedy because the discovery sought was not relevant to any issue in the case under Federal Rule of Civil Procedure 26. The district court found it was not enough that Amgen had filed suit under § 271(e)(2)(C) on another patent. In effect, to get discovery of the manufacturing

information withheld by Hospira, Amgen would have needed sufficient information about Hospira's secret manufacturing processes to initiate a patent infringement lawsuit under § 271(e)(2)(C) *without* the information Hospira withheld. Thus, by withholding the manufacturing information from its paragraph (2)(A) disclosure, Hospira prevented Amgen from having the factual basis necessary to bring an infringement action on its cell-culture patents.

In short, the Court can resolve the issue on appeal (*i.e.*, whether discovery is available to Amgen in a patent infringement action under § 271(e)(2)(C) to remedy Hospira's failure to provide manufacturing information in accordance with paragraph 2(A)) without considering the merits of any of the counts in Amgen's Amended Complaint (*i.e.*, whether Hospira has infringed Amgen's asserted patents and whether Hospira has violated the 180-day notice requirement of paragraph (8)(A)).

The issue presented in this appeal raises an important public interest under the BPCIA. If Hospira is able to rely on this Court's decision in *Amgen v. Sandoz* to withhold information expressly called for by paragraph (2)(A) in the BPCIA pre-suit process, and then refuse to provide discovery of that withheld information in a subsequent suit, Hospira and future biosimilar applicants will be able to evade detection of patent infringement and thereby deny Amgen and other Reference Product Sponsors access to the courts to protect their patent rights. Although this

Court recognized this concern in *Amgen v. Sandoz*, and ruled that Amgen could obtain the withheld information in discovery during an infringement action, 794 F.3d at 1355-56, the district court in this case found that Amgen may not discover Hospira's manufacturing information without having filed an infringement action on a patent that would make the manufacturing information relevant under Federal Rule of Civil Procedure 26.

Accordingly, this appeal raises an important issue that is completely separate from the merits of the underlying case.

3. The district court's order is not effectively reviewable on appeal from final judgment because it will categorically deny Sponsors the opportunity to seek pre-marketing injunctions on process patents

Hospira argues that the Court lacks jurisdiction because the issue on appeal is reviewable following final judgment. But the issue would not be *effectively* reviewable following final judgment. The BPCIA affords an RPS (like Amgen) a unique set of rights including a jurisdictional act of infringement (35 U.S.C. § 271(e)(2)(C)), information from which its patent rights can be assessed (*e.g.*, 42 U.S.C. § 262(*l*)(2)(A), (3)(B) and (4)), a mandatory injunction remedy (§ 271(e)(4)(D)), and a 180-day period after licensure in which to seek an injunction before first-marketing of the biosimilar product (§ 262(*l*)(8)). If the biosimilar applicant can withhold manufacturing information under paragraph (2)(A), refuse to provide it in discovery, and delay appellate review until final

judgment is entered, these rights under the BPCIA would be effectively denied with respect to manufacturing patents.

The BPCIA provides for disclosure of the applicant's manufacturing information concurrent with FDA review of the aBLA so that the sponsor can assess and act on its patent rights *before* the applicant begins to commercialize its biosimilar product following FDA licensure. Deferred appellate review of this issue would be tantamount to denying the sponsor a remedy for the applicant's non-compliance with paragraph (2)(A) and denying an opportunity for pre-commercialization patent enforcement and remedies that the BPCIA provides. Because this issue implicates a narrow class of appealable issues in a new area of law, review under the collateral order doctrine is warranted.

a. The disclosure requirement of paragraph (2)(A) permits the identification and resolution of patent disputes *before* an applicant receives FDA approval and launches its biosimilar product

Through paragraph (2)(A), the BPCIA requires Hospira to provide, in addition to its aBLA, "information that describes the process or processes used to manufacture the biological product that is the subject of such application." This ensures that Amgen has the facts to assess whether it "believes a claim of patent infringement could reasonably be asserted . . . , if a person . . . engaged in ***the making*** . . . of the biological product." 42 U.S.C. § 262(*l*)(3)(A) (emphasis added).

Under this Court's ruling in *Amgen v. Sandoz*, Amgen may obtain Hospira's manufacturing information before Hospira launches its product. In *Amgen*, this Court repeatedly referred to the information described in paragraph (2)(A) as "required information." 794 F.3d at 1355-56. This Court held that when a biosimilar applicant (here, Hospira) refuses to provide this required information during the BPCIA information exchange, an RPS (here, Amgen) may bring a patent-infringement suit and "access the required information through discovery." *Id.* at 1356. Otherwise, an applicant such as Hospira could "unlawfully evade[] the detection of process patent infringement" by refusing to provide the required information. *Id.* at 1355. If Amgen must await final judgment in this case before appealing the district court's ruling, Amgen will almost certainly be unable to obtain the manufacturing information before Hospira launches its product. In that case, Amgen would lose its opportunity to assess its patent rights, sue for patent infringement, and obtain remedies *before* Hospira begins marketing its biosimilar product.

b. The issue raised on appeal falls within a narrow class of decisions that collectively raise an important public interest under the BPCIA

In assessing whether appellate review is available under the collateral order doctrine, courts consider whether "the entire category to which a claim belongs" warrants collateral review. *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 107

(2009) (quoting *Digital Equipment Corp. v. Desktop Direct, Inc.*, 511 U.S. 863, 868 (1994)). "[T]he decisive consideration is whether delaying review until the entry of final judgment 'would imperil a substantial public interest' or 'some particular value of a high order.'" *Id.* (quoting *Will v. Hallock*, 546 U.S. 345, 352-53 (2006)). This inquiry focuses on whether the "class of claims, taken as a whole, can be adequately vindicated by other means." *Id.*

Properly defined, the "class of claims" implicated by Amgen's appeal is narrow. It comprises appeals from similar cases where an RPS has alleged that a biosimilar applicant failed to produce required information under paragraph (2)(A) but the district court has denied discovery of that information. While this class of claims may arise in the context of discovery, denial of this information is tantamount to denying an RPS its sole remedy under paragraph (2)(A). According to this Court in *Amgen v. Sandoz*, the only remedy for a violation of the paragraph (2)(A) production requirement is to file an infringement suit and seek the required information in discovery. 794 F.3d at 1356-57. Although under that decision, Amgen may not sustain a separate cause of action for relief under paragraph (2)(A), Amgen has pled in its complaint all the facts necessary to establish Hospira's violation of the paragraph (2)(A) requirement. (Labbé Decl. Ex. A ¶¶ 44-53.) By doing so, Amgen pled the requisite foundational facts to obtain through discovery the manufacturing information withheld in Hospira's paragraph (2)(A)

disclosure—the very information Amgen needed to evaluate whether there exists a reasonable basis to assert infringement of its other manufacturing patents.

Hospira places undue emphasis on cases finding that routine discovery orders are not appealable under the collateral order doctrine. These cases are only relevant to Hospira's straw-man argument that this appeal raises a routine discovery issue. Instead, this appeal presents an issue of law regarding the interpretation of the BPCIA (a federal statute) and this Court's ruling in *Amgen v. Sandoz*.

c. Without an immediate appeal, Amgen would effectively lose its ability to enforce its process patents under the BPCIA's pre-marketing regime and to seek the unique pre-marketing remedies the BPCIA affords

The touchstone of the collateral order doctrine is not whether an issue *could* be reviewed on appeal following final judgment, but whether the issue can be *effectively* reviewed after final judgment. For example, this Court has found that an order unsealing confidential information is appealable under the collateral order doctrine because once the "parties' confidential information is made publicly available, it cannot be made secret again." *Apple*, 727 F.3d at 1220; *see also Virginia Dep't of State Police v. Washington Post*, 386 F.3d 567, 574 n.4 (4th Cir. 2004) ("[A]n order unsealing district court documents is an appealable collateral order . . . ."). Likewise, courts have routinely found that orders denying claims of

absolute, qualified, and sovereign immunity are appealable under the collateral order doctrine because these immunities provide immunity from *suit*, and if the protected party must first stand trial before appealing denial of immunity, the party would effectively lose its immunity. *Puerto Rico Aqueduct & Sewer Authority v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 147 (1993) (sovereign immunity under the Eleventh Amendment); *Mitchell v. Forsyth*, 472 U.S. 511, 524-530 (1985) (qualified immunity); *Nixon*, 457 U.S. at 742 (absolute immunity).

Here, Amgen seeks to review Hospira's manufacturing information and assess its patent rights *before* Hospira launches its biosimilar product. If Amgen must await the final judgment in this case, it will not have an opportunity to obtain Hospira's manufacturing information before launch. Thus, although Amgen *could* raise this issue on appeal following final judgment, it could not *effectively* do so, because by then, its rights under the BPCIA to pre-marketing review, suit, and remedies will be lost.

The BPCIA "ensure[s] that litigation surrounding relevant patents will be resolved expeditiously and *prior to the launch* of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." *Amgen*, 794 F.3d at 1363 (Newman, J., concurring) (quoting *Biologics and Biosimilars*, 111th Cong. 9 (July 14, 2009) (statement of Rep. Eshoo)). This Court recently reiterated that the patent litigation procedures under the BPCIA are

intended to permit resolution of patent disputes *before* a biosimilar applicant launches its product. *Amgen Inc. v. Apotex Inc.*, Appeal No. 2016-1308, slip op. at 17-18 (Fed. Cir. July 5, 2016).

The BPCIA's requirement that Amgen be permitted to assess its patent rights before Hospira launches is consistent with this Court's decisions recognizing that the launch of a lower-priced version of a branded product can cause irreparable injury to the branded competitor. *See, e.g.*, *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155 (Fed. Cir. 2011) (explaining that "money damages alone cannot fully compensate" plaintiff for "irreparable harm due to lost market share, lost business opportunities, and price erosion"); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (upholding district court's finding of irreparable harm where there was a "likelihood of price erosion and loss of market position without corresponding market expansion from the introduction of [competitor's] product").

d. The law is unsettled and in need of immediate clarification

The law under paragraph (2)(A) is new and unsettled as to the various maneuvers that biosimilar applicants will make to avoid an RPS's patent rights. In *Mohawk*, the Court found that disclosure orders adverse to the attorney-client privilege do not qualify for review under the collateral order doctrine in part because "[m]ost district court rulings on these matters involve the routine

application of settled legal principles. They are unlikely to be reversed on appeal, particularly when they rest on factual determinations for which appellate deference is the norm." 558 U.S. at 110; *see also Nixon*, 457 U.S. at 742 (finding collateral-order review appropriate where the issues "present a serious and unsettled question").

Unlike in *Mohawk*, the issue in this appeal arises under a new and unaddressed area of law. Only a handful of infringement cases have been filed under the BPCIA, and this Court has only once ruled on an issue under paragraph (2)(A). *Amgen v. Sandoz*, 794 F.3d at 1356-57.[2] By clarifying the law under *Amgen v. Sandoz*, this Court will give guidance to biosimilar applicants as to their disclosure obligations under the statute.

B. The Court should prevent delay by denying Hospira's motion

The Court should deny Hospira's Motion to Dismiss because this Court has jurisdiction over this appeal under the collateral order doctrine. Alternatively, rather than potentially delay briefing and consideration of this appeal, Amgen submits that the better course is for Hospira to present its arguments for dismissal in its principal brief. Under Federal Circuit Rule 27(f), a motion to dismiss for lack of jurisdiction "should be made as soon after docketing as the grounds for the

[2] This Court's decision in *Amgen v. Sandoz* is currently the subject of pending petitions for a writ of certiorari before the Supreme Court. Case Nos. 15-1039, 15-1195.

motion are known." Yet, Hospira waited until July 8 to file its Motion to Dismiss, more than a month after the Court docketed this appeal on June 7. The Court should deny Hospira's motion on this ground to prevent any delay in briefing this appeal.

IV. CONCLUSION

For all of the foregoing reasons, the Court should deny Hospira's Motion to Dismiss.

Date: July 18, 2016

Respectfully submitted,

/s/ John R. Labbé

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT
Amgen Inc. and Amgen Manufacturing, Limited v. Hospira, Inc., No. 16-2179

CERTIFICATE OF INTEREST

Counsel for the: Appellant
certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me:

   AMGEN INC. and AMGEN MANUFACTURING, LIMITED

2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:

   same as above

3. Parent corporations and publicly held companies that own 10 % or more of stock in the party:

   AMGEN INC.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

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Date: July 18, 2016

/s/ John R. Labbé
John R. Labbé

Appeal No. 16-2179

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,
Plaintiffs-Appellants,

v.

HOSPIRA, INC.,
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Appeal from the United States District Court for the District of Delaware in Case No. 1:15-cv-00839-RGA, Judge Richard G. Andrews

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DECLARATION OF JOHN R. LABBÉ

I, John R. Labbé, declare as follows:

1. I am a partner at the law firm of Marshall, Gerstein & Borun LLP, counsel to Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") in the above-captioned action. I was admitted to this Court on March 26, 2009. Pursuant to Federal Circuit Rule 27(b)(1), I submit this declaration in support of Amgen's Opposition to Hospira, Inc.'s Motion to Dismiss Amgen Inc. and Amgen Manufacturing, Limited's Appeal for Lack of Jurisdiction.

2. Attached as Exhibit A is a true and correct copy of Amgen's Amended Complaint filed in the district court on November 6, 2015.

3. Attached as Exhibit B is a true and correct copy of a letter dated March 31, 2015 from Kevin M. Flowers, counsel for Amgen, to Thomas J. Meloro,

counsel for Hospira, Inc. ("Hospira"). Confidential information that is not necessary to the resolution of the pending Motion is redacted.

4. Attached as Exhibit C is a true and correct copy of a letter dated April 27, 2015 from Kevin M. Flowers to Michael W. Johnson, counsel for Hospira.

5. Attached as Exhibit D is a true and correct copy of a letter dated May 1, 2015 from Kevin M. Flowers to Michael W. Johnson. Confidential information that is not necessary to the resolution of the pending Motion is redacted.

6. Attached as Exhibit E is a true and correct copy of a letter dated April 21, 2015 from Michael W. Johnson to Kevin M. Flowers. Confidential information that is not necessary to the resolution of the pending Motion is redacted.

7. Attached as Exhibit F is a true and correct copy of a letter dated April 30, 2015 from Michael W. Johnson to Kevin M. Flowers.

8. Attached as Exhibit G is a true and correct copy of Amgen's letter brief filed in the district court on May 2, 2016 addressing the issue now on appeal.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on the 18th day of July, 2016.

/s/ John R. Labbé
John R. Labbé

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,	)	
Plaintiffs,	)	
v.	)	C.A. No. 15-839 (RGA)
HOSPIRA, INC.,	)	**DEMAND FOR JURY TRIAL**
Defendant.	)	

AMENDED COMPLAINT

Amgen Inc. and Amgen Manufacturing, Limited (collectively "Amgen"), by and through their undersigned attorneys, for their Amended Complaint against Hospira, Inc. ("Hospira") pursuant to Federal Rule of Civil Procedure 15(a)(1)(B), hereby allege:

THE PARTIES

1. Amgen Inc. is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California, 91320.

2. Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico.

3. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. Founded in 1980, Amgen is a pioneer in the development of biological human therapeutics. Today, Amgen is the largest biotechnology company in the world, fueled in part by the success of its first therapeutic product EPOGEN® (epoetin alfa).

4. On information and belief, defendant Hospira is a corporation existing under the laws of the state of Delaware, with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

5. On information and belief, Hospira, founded in 2004, is in the business of manufacturing and selling generic injectable products, and is seeking to expand its U.S. business into the manufacture and sale of biosimilar biologic therapeutics.

NATURE OF THE ACTION

6. This is one of the first actions for patent infringement under 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA"), and is the first such action in this District.

7. This is also one of the first actions seeking to give meaning and force to the disclosure and notice provisions of the BPCIA.

8. By amendment to the Public Health Service Act ("the PHSA"), the BPCIA created a new, abbreviated pathway for the approval of biological products that are highly similar to previously-licensed innovative biological products. The abbreviated pathway (42 U.S.C. § 262(k), often referred to as "the subsection (k) pathway") allows a biosimilar applicant to secure a license from the Food and Drug Administration ("the FDA") by relying on the prior license granted to the innovator company ("the Reference Product Sponsor" or "RPS") for its innovative biological product ("the reference product"), provided that the reference product had been licensed by the FDA under the innovator pathway (42 U.S.C. § 262(a), often referred to as "the subsection (a) pathway"), which has traditionally required proof of safety and efficacy through a series of phased clinical trials.

9. In addition to creating an abbreviated pathway for approval, the BPCIA amended the PHSA to create an intricate and carefully orchestrated set of procedures for the biosimilar applicant and the Reference Product Sponsor to engage in a private and confidential disclosure of information, exchange of contentions, conduct of negotiations, and notice of commercial marketing to identify patents in dispute, resolve or narrow those disputes, and, if court

intervention is necessary, to facilitate an informed and orderly preliminary injunction practice after FDA licensure of the biosimilar product but before the status quo in the marketplace is disturbed. These procedures are set forth in 42 U.S.C. § 262(*l*) ("the patent provisions" of the BPCIA).

10. Seeking the benefits of the subsection (k) pathway, Hospira submitted its Biologic License Application ("BLA") No. 125545 ("the Hospira BLA") to the FDA, requesting that its biological product ("the Hospira Epoetin Biosimilar Product") be licensed by relying on Amgen's demonstration of the safety and efficacy of EPOGEN® (epoetin alfa).

11. Despite seeking the benefits of the subsection (k) pathway by relying on Amgen's EPOGEN® license, Hospira has repeatedly refused to comply with its obligations under the patent provisions of the BPCIA.

12. In part, this lawsuit is necessary because Hospira has chosen to withhold the manufacturing information that 42 U.S.C. § 262(*l*)(2)(A) required Hospira to provide to Amgen within 20 days of the FDA having accepted Hospira's biosimilar application for review. Hospira has thereby limited Amgen's ability to identify patents that could reasonably be asserted against Hospira, forcing Amgen to initiate this lawsuit to get the withheld information through discovery.

13. In part, this lawsuit is necessary because Hospira has refused to engage in the good-faith negotiations with Amgen required by 42 U.S.C. § 262(*l*)(4), thereby necessitating this Court's intervention to resolve the patent disputes identified so far.

14. In part, this lawsuit is necessary because Hospira has declared that it will not comply with 42 U.S.C. § 262(*l*)(8)(A), which requires Hospira to provide Amgen with 180 days'

notice of its first commercial marketing, on or after FDA licensure of the Hospira Epoetin Biosimilar Product.

15. Further, this lawsuit is necessary because Hospira has infringed patents that Amgen has identified under 42 U.S.C. § 262(*l*)(3)(A) and, upon information and belief, Hospira will infringe one or more claims of these patents should it commercially manufacture, use, offer for sale, sell, or import into the United States the Hospira Epoetin Biosimilar Product.

JURISDICTION AND VENUE

16. This is an action to declare the rights and obligations of the parties under Section 262 of the PHSA, Title 42, United States Code, and for patent infringement under the patent laws of the United States, Title 35, United States Code. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

17. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 (b) and (c), and 28 U.S.C. § 1400(b). On information and belief, Hospira manufactures, seeks regulatory approval to market, distribute, and sell pharmaceutical products, and markets, distributes, and sells pharmaceutical products for use throughout the United States, including in this District.

18. This Court has personal jurisdiction over Hospira by virtue of, among other things, Hospira being a Delaware corporation, having conducted business in this District, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with Delaware.

BACKGROUND

A. Amgen's innovative biological product, EPOGEN® (epoetin alfa)

19. The active ingredient in Amgen's innovative drug EPOGEN® (epoetin alfa) is recombinant human erythropoietin, a 165-amino-acid glycoprotein that is produced by genetically modified animal cells grown in culture vessels. By binding to specific receptors on

the surface of certain types of cells in the bone marrow, EPOGEN® (epoetin alfa) stimulates the production of red blood cells, known as erythrocytes. EPOGEN® (epoetin alfa) is used to treat anemia. Patients with anemia have a lower-than-normal level of red blood cells. EPOGEN® (epoetin alfa) is used to reduce or avoid the need for red blood cell transfusions in patients, for example, with chronic kidney disease.

20. Amgen is the recognized pioneer for developing therapeutically effective biological products to treat, ameliorate, or prevent disease. The availability of EPOGEN® represented a major advance in the treatment of anemia.

21. Biological products for human therapeutic use are regulated by the FDA under the PHSA. (In contrast, chemical pharmaceuticals are regulated by the FDA under the Food, Drug and Cosmetic Act.) A company seeking to market a biological product for human therapeutic use in the United States must first submit a BLA to obtain a license from the FDA. Developers of innovative biological products typically go through three clinical development phases to develop evidence of the safety and efficacy of the biological product for use in defined disease states before seeking FDA approval: Phase I, which typically tests safety, tolerability, and pharmacologic properties on healthy human volunteers, and Phases II and III, which typically test safety and efficacy on, respectively, a small and then a larger group of afflicted patients. If testing in each phase succeeds, the innovator may be in a position to submit a BLA under 42 U.S.C. § 262(a) seeking FDA approval. The BLA includes, among other things, technical data on the characterization and composition of the biological product, toxicology studies of the product in animals, the means for manufacturing the product, clinical trial results to establish the safety, efficacy, and dosing of the product for specific patient populations and disease states, and labeling for use of the product for which approval is requested. 21 C.F.R. §§ 601 *et seq.*

22. After submission of the BLA, innovators must pass demanding stages of clearance. For example, innovators are required to demonstrate to the FDA that "the biological product that is the subject of the application is safe, pure, and potent" (42 U.S.C. § 262(a)(2)(C)(i)(I)); and "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(II). If the FDA determines that the biological product or the facility does not meet the requirements, the BLA will be denied.

23. Not surprisingly, the development of innovative pharmaceutical products requires the investment of enormous amounts of time and money. For example, it typically takes ten years to develop a drug, and the average cost to develop a drug (including the cost of failures) has been estimated at $2.6 billion. *See* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 2015 PROFILE: BIOPHARMACEUTICAL RESEARCH INDUSTRY at 35.[1]

24. Amgen went through each of the requirements of the subsection (a) pathway to obtain a license from the FDA for its innovative biological product EPOGEN® (epoetin alfa). As a result, in 1989, the FDA approved EPOGEN® (epoetin alfa) pursuant to BLA No. 103234, for the treatment of anemia associated with chronic renal failure ("CRF") (including end-stage renal disease). The initial approval of EPOGEN® (epoetin alfa) for use in treating anemia due to chronic renal failure was followed by approvals for additional indications: for use in patients with certain cancers suffering from anemia due to concomitant chemotherapy, in patients with HIV-infection with anemia due to anti-viral drugs, and to decrease the need for transfusion in patients scheduled for certain types of surgery. Since being granted approval, Amgen has

[1] *Available at* http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.

manufactured and sold EPOGEN® (epoetin alfa) in the U.S. for the treatment of anemia associated with chronic kidney disease in patients on dialysis. Amgen also manufactures and supplies epoetin alfa to Ortho Biotech, a division of Johnson & Johnson, for sale in the United States under the tradename PROCRIT® for the treatment of anemia in chronic kidney disease patients who are not receiving dialysis, as well as for other FDA-approved therapeutic indications.

B. Hospira seeks approval to market a biosimilar version of EPOGEN® (epoetin alfa) by taking advantage of the abbreviated subsection (k) pathway of the BPCIA

25. Hospira is seeking approval from the FDA to sell a "biosimilar" version of EPOGEN® (epoetin alfa) by taking advantage of a new, abbreviated approval pathway under the BPCIA.

26. But Hospira has chosen to ignore certain statutory requirements of the BPCIA that Congress put in place to protect innovators such as Amgen. Rather than follow the requirements of the BPCIA, Hospira has selectively decided to comply with certain provisions while refusing to comply with others.

C. The BPCIA reflects Congress's balancing of the interests of innovators and biosimilar applicants

27. Congress enacted the BPCIA on March 23, 2010. The purpose of the BPCIA is to establish "a biosimilars pathway balancing innovation and consumer interests." Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) (amending 42 U.S.C. § 262). The statutory requirements of the BPCIA reflect Congress's intent to achieve this balance.

28. On one side of the balance, the BPCIA created an abbreviated approval pathway, 42 U.S.C. § 262(k), for FDA licensure of biological products upon a determination that the

biological product is "biosimilar" to a previously-licensed "reference product." The BPCIA defines a "biosimilar" to be a biological product that: (1) is "highly similar to the reference product notwithstanding minor differences in clinically inactive components," and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. §§ 262(i)(2)(A) and (B). The BPCIA defines a "reference product" to be "a single biological product licensed under subsection (a) against which the biological product is evaluated in an application submitted under subsection (k)." 42 U.S.C. § 262(i)(4).

29. As opposed to applicants following the § 262(a) pathway, biosimilar applicants following the § 262(k) pathway have the advantage of referencing the innovator's license—the FDA evaluates the safety and efficacy of the applicant's biological product by relying on the innovator's prior demonstration of safety, purity, and potency of the reference product. Specifically, the § 262(k) pathway may only be used where the prior applicant for the reference product ("the Reference Product Sponsor," or "RPS") has submitted an application under 42 U.S.C. § 262(a) for approval of a reference product, and the FDA has determined that the RPS has demonstrated that "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I).

30. Before the BPCIA, reference to another's biological license could be made only with the permission of the innovator RPS. An innovator RPS enjoyed permanent and exclusive rights to its clinical trial data and FDA license. The BPCIA advanced the public's interest in price competition in part by diminishing these rights, allowing a biosimilar applicant to "reference" the innovator RPS's license rather than incurring the delay and costs of generating its own clinical data.

31. Consequently, the § 262(k) pathway allows the biosimilar applicant to avoid the time and expense incurred by the RPS for development and clinical testing, and to gain licensure to commercialize its biological product in the market sooner as a biosimilar than it could have done through an independent demonstration of safety, purity, and potency under the § 262(a) pathway. The § 262(k) pathway is thus referred to as an "abbreviated" approval pathway.

32. In addition to providing these benefits, approval under the § 262(k) pathway offers another benefit to the biosimilar applicant: a product that is approved as a biosimilar can take advantage of the existing market for the reference product created by the RPS.

33. On the other side of the balance, Congress implemented a detailed procedure to protect the interests of the RPS, tying this procedure to the biosimilar applicant's choice to submit a BLA under, and gain the benefit of, the abbreviated § 262(k) pathway. 42 U.S.C. § 262(*l*)(1)(B)(i). This procedure compels biosimilar applicants that choose the abbreviated § 262(k) pathway to provide the RPS with a defined set of information shortly after the FDA accepts the biosimilar applicant's BLA for review.

34. Of particular relevance here, in 42 U.S.C. § 262(*l*), the BPCIA sets forth requirements that the biosimilar applicant must follow to obtain the benefits of filing its BLA under the § 262(k) pathway. Specifically, 42 U.S.C. § 262(*l*) provides the following series of steps for the disclosure of information, the exchange of contentions, the resolution or narrowing of patent disputes, and, if necessary, the commencement of litigation, all within specified times triggered initially by the biosimilar applicant's submission and the FDA's acceptance of a BLA under the § 262(k) pathway:

> ***a.*** ***Within 20 days*** after the FDA has accepted its abbreviated application, the biosimilar applicant must provide the Reference Product Sponsor: (i) a copy of the biosimilar application and (ii) other information describing the

process(es) for manufacturing the biosimilar product. 42 U.S.C. § 262(*l*)(2).

b. ***Within 60 days*** after receiving the BLA and manufacturing information, the Reference Product Sponsor must provide the biosimilar applicant with a list of all patents that the Reference Product Sponsor believes a claim for patent infringement could reasonably be asserted by either the Reference Product Sponsor or a patent owner that has granted exclusive rights to the Reference Product Sponsor. 42 U.S.C. § 262(*l*)(3)(A). The Reference Product Sponsor must also identify which, if any, of these patents it would be prepared to license to the biosimilar applicant. 42 U.S.C. § 262(*l*)(3)(A)(ii).

c. ***Within 60 days*** after receiving the foregoing list from the Reference Product Sponsor, the biosimilar applicant may provide to the Reference Product Sponsor a list of patents that the biosimilar applicant believes could be subject to a claim of patent infringement, 42 U.S.C. § 262(*l*)(3)(B)(i), and with regard to any patents listed by the Reference Product Sponsor or the biosimilar applicant, the biosimilar applicant must also provide: (I) a statement describing, on a claim-by-claim basis, a factual and legal basis for an opinion that a patent is invalid, unenforceable, or not infringed; or (II) a statement that the biosimilar applicant does not intend to market until the patent expires. 42 U.S.C. § 262(*l*)(3)(B)(ii). The biosimilar applicant must also provide a response to the Reference Product Sponsor's identification of any patents it would be prepared to license. 42 U.S.C. § 262(*l*)(3)(B)(iii).

d. ***Within 60 days*** after receiving the information described immediately above, the Reference Product Sponsor must provide, regarding each patent discussed in (I) above, a reciprocal statement describing, on a claim by claim basis, a factual and legal basis for an opinion that a patent will be infringed as well as a response to any statement regarding validity and enforceability. 42 U.S.C. § 262(*l*)(3)(C).

e. After this exchange of information, both parties must engage in good-faith negotiations to identify which patents, if any, should be subject to patent infringement litigation. 42 U.S.C. § 262(*l*)(4)(A). If the parties reach agreement ***within 15 days*** of starting negotiations, the Reference Product Sponsor must bring a patent-infringement action against the biosimilar applicant on the negotiated list of patents ***within 30 days*** of such agreement. 42 U.S.C. § 262(*l*)(6)(A). If the parties do not reach agreement ***within 15 days*** of starting negotiations, the biosimilar applicant must notify the Reference Product Sponsor of the number of patents it will provide in a second list, and the parties then simultaneously exchange within five days of this notice a list of patents that each party believes should be the subject of infringement litigation. 42 U.S.C. § 262(*l*)(5). ***Within 30 days*** after exchanging these lists, the Reference Product

Sponsor must bring an "immediate" patent infringement action against the biosimilar applicant on all patents on these simultaneously exchanged lists. 42 U.S.C. § 262(*l*)(6)(B).

f. Even after the litigation contemplated by 42 U.S.C. § 262(*l*)(6)(B) has commenced, the Reference Product Sponsor must identify additional patents that are newly issued or licensed after the Reference Product Sponsor provided its patent list under 42 U.S.C. § 262(*l*)(3)(A). Specifically, the Reference Product Sponsor must, not later than 30 days after the issuance or licensing, supplement that list with the newly issued or licensed patent(s). 42 U.S.C. § 262(*l*)(7).

35. Section 262(*l*) also requires the biosimilar applicant to provide the RPS with at least 180 days' notice before the biosimilar applicant's first commercial marketing of the biosimilar product. 42 U.S.C. § 262(*l*)(8)(A) (the "subsection (k) applicant shall provide notice to the Reference Product Sponsor not later than 180 days before the date of first commercial marketing of the biological product licensed under subsection (k)"). The notice of commercial marketing can only be provided *on or after* the biosimilar applicant has received FDA approval to market its product. *Amgen Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015) ("[U]nder paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product."). The biosimilar applicant's obligation to provide this advance notice of commercial marketing is mandatory; it is not conditioned on performance of any act by the RPS, nor exempted if the biosimilar applicant fails to make the initial disclosures under 42 U.S.C. § 262(*l*)(2)(A). *Amgen*, 794 F.3d at 1359 ("A question exists, however, concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is."); *id.* at *1359-60 ("Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*). . . . Unlike the actions described in paragraphs (*l*)(3) through (*l*)(7), which all depend on, or are triggered by, the disclosure under paragraph (*l*)(2)(A), nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*).").

36. The 180-days' notice of commercial marketing enables the RPS to seek a preliminary injunction before the biosimilar applicant commences commercial marketing of the biosimilar product, enjoining the biosimilar applicant from commercially manufacturing or selling the biosimilar product until the court decides any disputed patent issues. Accordingly, this provision gives the courts an opportunity to consider the RPS's motion for preliminary injunction when the issues are fully crystallized and before the status quo has changed.

D. Hospira seeks the benefits of the BPCIA pathway under 42 U.S.C. § 262(k) but refuses to comply with all of its obligations under § 262(*l*)

1. The Hospira BLA

37. In December 2014, Hospira submitted the Hospira BLA to the FDA under the abbreviated § 262(k) pathway to obtain approval to commercially manufacture, market, and sell the Hospira Epoetin Biosimilar Product, a biosimilar version of EPOGEN® (epoetin alfa) (which Hospira refers to as "Hospira Epoetin") for treating particular diseases in the United States.

38. The Hospira Epoetin Biosimilar Product is designed to copy and compete with Amgen's EPOGEN® (epoetin alfa). Hospira will instruct or direct others to administer the Hospira Epoetin Biosimilar Product to certain patients in the U.S. to treat particular diseases in the same way that Amgen's EPOGEN® (epoetin alfa) is administered. Hospira is seeking FDA approval for one or more indications for which EPOGEN® (epoetin alfa) is already approved.

39. Hospira does not seek to independently demonstrate to the FDA that its biological product is "safe, pure, and potent" pursuant to 42 U.S.C. § 262(a), as Amgen did in its BLA for its innovative biological product EPOGEN® (epoetin alfa). Rather, Hospira has requested that the FDA evaluate the suitability of its biological product for licensure by expressly referencing EPOGEN® (epoetin alfa) and thereby relying on the data supporting Amgen's FDA license for EPOGEN® (epoetin alfa) 42 U.S.C. § 262(k)(2)(A)(iii)(I).

40. On February 23, 2015, Hospira notified Amgen that the Hospira BLA had "recently been accepted for filing by FDA." On information and belief, the FDA has not yet approved the Hospira BLA or given any indication whether it will be approved, when it will be approved, or what the scope of any approval will be. Under the Biosimilar Biological Product Authorization Performance Goal and Procedures, which sets forth FDA goals for fiscal years 2013-2017, the FDA is committed to reviewing and acting "on 70 percent of original biosimilar biological product application submissions within 10 months of receipt" for biosimilar biological product applications filed in 2014.[2] Therefore, the FDA may complete its final review of the Hospira Epoetin Biosimilar Product before November, 2015.

41. Hospira's choice to submit its BLA using the abbreviated subsection (k) pathway triggered its mandatory obligation to also comply with the disclosure obligations at the outset of FDA review. 42 U.S.C. § 262(*l*)(1)(B)(i).

42. Hospira's receipt of FDA notification that its BLA had been accepted for review triggered the 20-day deadline to provide its BLA and manufacturing information to Amgen as required by 42 U.S.C. § 262(*l*)(2)(A).

43. Purporting to comply with § 262(*l*)(2)(A), on March 3, 2015, Hospira provided a copy of its BLA for the Hospira Epoetin Biosimilar Product to Amgen.

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[2] FDA, Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 through 2017, *available at* http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf.

2. Hospira violated § 262(*l*)(2)(A)

44. Although Hospira provided a copy of the Hospira BLA to Amgen, it did not provide Amgen with the other information describing the processes used to manufacture the Hospira Epoetin Biosimilar Product as required by § 262(*l*)(2)(A).

45. In correspondence dated March 31, April 17, April 27, and May 1, 2015, Amgen specifically identified for Hospira the manufacturing information that was missing from the Hospira BLA. Amgen repeatedly requested that Hospira comply with § 262(*l*)(2)(A) and provide that information.

46. In correspondence dated March 5, April 21, April 30, August 19, and September 15, 2015, Hospira repeatedly refused to provide Amgen with the other information describing the processes used to manufacture the Hospira Epoetin Biosimilar Product as required by § 262(*l*)(2)(A).

47. Hospira deliberately decided not to provide Amgen with the information necessary to describe the processes for manufacturing the Hospira Epoetin Biosimilar Product within 20 days of receiving notification of FDA acceptance of its application for review.

48. To date, Amgen still has not received this manufacturing information, while Hospira continues to enjoy the benefit of FDA review of its application in reliance on Amgen's prior biological product license for EPOGEN® (epoetin alfa).

49. In *Amgen Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), the Federal Circuit held that Sandoz's failure to provide its BLA and other manufacturing information to Amgen as required by 42 U.S.C. § 262(l)(2)(A), did not violate the BPCIA. The panel majority held that because the BPCIA provides consequences for a biosimilar applicant's failure to comply with § 262(*l*)(2)(A), the word "'shall' in paragraph § 262(*l*)(2)(A) does not mean 'must.'" *Id.* at 1355. The majority held instead that if the applicant fails to provide the required information, the RPS

may bring a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii), and obtain the required information through discovery. *Id.* at 1356. Judge Newman dissented, because the BPCIA "leaves no uncertainty as to which of its provisions are mandatory and which are permissive," with § 262(*l*)(2)(A) being mandatory, and because § 262(*l*)(2)(A) is central to the entire BPCIA: "Subsection (k) and subsection (*l*) are components of an integrated framework; to enjoy the benefits of subsection (k), the biosimilar applicant is obligated to comply with subsection (*l*)," and an applicant that fails to provide the required information violates the "explicit balance of obligations and benefits" of the BPCIA. *Id.* at 1365-66.

50. Receipt of the required manufacturing information would have given Amgen the opportunity to evaluate the manufacturing processes used by Hospira to determine whether those processes would infringe any patents held by Amgen, including under 35 U.S.C. § 271(a), (b), (c), (e), or (g). The purpose of the statutory requirements of 42 U.S.C. § 262(*l*)(2) is, among other things, to permit such an evaluation. In the absence of such a disclosure, the Reference Product Sponsor has no access to the manufacturing information.

51. Had Hospira provided Amgen with the required manufacturing information, Amgen would have been in a position: (1) to provide to Hospira a list of all patents for which Amgen believes a claim of patent infringement could reasonably be asserted as to the Hospira Epoetin Biosimilar Product, and (2) to identify to Hospira whether Amgen would be prepared to grant a license to Hospira under each of the patents included on such a list. 42 U.S.C. § 262(*l*)(3)(A). Amgen has an extensive portfolio of patents relating to various aspects of the manufacture of biological products. Because Hospira's manufacturing process for the Hospira Epoetin Biosimilar Product is still secret, however, without the disclosure required by 42 U.S.C.

§ 262(*l*)(2), Amgen cannot conduct a full and complete evaluation of its patent portfolio as to Hospira's specific processes of manufacture. By unlawfully withholding the information required by 42 U.S.C. § 262, Hospira has thereby frustrated the statutory purpose and deprived Amgen of the opportunity to seek redress for potential infringement.

52. Amgen may therefore seek to assert additional patents following eventual receipt of Hospira's manufacturing information to be produced in discovery in this action under the Federal Rules.

53. Hospira's actions also create the substantial and continuing risk that Amgen cannot obtain manufacturing information regarding the Hospira Epoetin Biosimilar Product that would permit Amgen to assert its process patents before commercialization of that product. Forcing Amgen to assert one or more of its patents (including process patents) after Hospira's commercial entry into the market harms Amgen by, *e.g.*, diminishing the value of such patents.

3. Amgen has complied with the BPCIA procedures

54. Amgen complied (to the extent possible, given Hospira's non-compliance) with its obligations under the BPCIA.

55. Within 60 days after receiving a copy of the Hospira BLA, Amgen provided Hospira with a list of patents that Amgen believed could reasonably be asserted by Amgen if a person not licensed under the patents engaged in the manufacture, use, sale, offer for sale, or import into the United States of the Hospira Epoetin Biosimilar Product, thus satisfying 42 U.S.C. § 262(*l*)(3)(A)(i). Amgen also provided the required statement as to which, if any, of these patents it would be prepared to license to Hospira, thus satisfying 42 U.S.C. § 262(*l*)(3)(A)(ii).

56. Within 60 days after receiving Hospira's statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) (which did not satisfy the statute's requirement that Hospira address each patent

on a claim-by-claim basis), Amgen provided its reciprocal statement under 42 U.S.C. § 262(*l*)(3)(C), describing, on a claim-by-claim basis, the factual and legal bases for Amgen's opinion that each patent will be infringed, as well as a response to Hospira's statement regarding validity and enforceability (to the extent Hospira provided such a statement).

4. Hospira violated § 262(*l*)(4)

57. Beginning on August 18, 2015, Amgen sought to comply with the requirements of 42 U.S.C. § 262(*l*)(4)(A) to engage in "good-faith negotiations" with Hospira to "agree on which, if any, patents . . . shall be the subject of an action for patent infringement under [42 U.S.C. § 262(*l*)(6)]."

58. Hospira refused to engage in any of the negotiations required by 42 U.S.C. § 262(*l*)(4)(A). Instead, in correspondence dated August 19, August 24, and September 15, 2015, Hospira purported to bypass its obligations by merely declaring that it was "accepting" the patents that Amgen had initially listed in accordance with § 262(*l*)(3)(A).

59. In correspondence dated August 21 and September 14, 2015, respectively, Amgen thereafter sought to gain Hospira's cooperation to commence good-faith negotiations with the goal of resolving or narrowing the issues to be put before the Court. Hospira has steadfastly refused to engage in *any* negotiation with Amgen, in violation of the statute.

5. Hospira violated § 262(*l*)(8)(A)

60. Under 42 U.S.C. § 262(*l*)(8)(A), Hospira is also required to provide Amgen with at least 180 days' notice of the date of first commercial marketing of the licensed Hospira Epoetin Biosimilar Product. At product licensure, when the issues are fully crystalized and the threat of injury is imminent, this provision will permit Amgen to assess its patent rights and seek injunctive relief before the status quo in the marketplace has changed, *i.e.*, before Hospira first

markets commercially or launches the Hospira Epoetin Biosimilar Product. It avoids the need for emergency motions and the attendant disruption to the Court's administration of its docket.

61. Hospira's obligation to provide this notice of commercial marketing is not conditioned on performance of any act by Amgen, and Hospira must provide the notice *on or after* the date that the FDA approves its biosimilar application. *Amgen Inc. v. Sandoz, Inc*., 794 F.3d 1347, 1357 (Fed. Cir. 2015) ("[U]nder paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product"); *id.* at 1359-60 ("Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (l). . . . Unlike the actions described in paragraphs (*l*)(3) through (*l*)(7), which all depend on, or are triggered by, the disclosure under paragraph (*l*)(2)(A), nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*).").

62. Despite its obligation under § 262(*l*)(8)(A), Hospira provided Amgen with a purported (8)(A) notice on April 8, 2015, *before* Amgen had provided its initial disclosure of patents under (3)(A) and *before* Hospira received FDA approval for its Hospira Epoetin Biosimilar Product. On May 8, 2015, Amgen objected to this premature attempt to provide notice, but Hospira has repeatedly refused to withdraw it.

63. On August 18, 2015, after the Federal Circuit issued its decision in *Amgen v. Sandoz* holding that the notice must be provided on or after FDA approval, Amgen renewed its objection and requested that Hospira confirm that it would follow the law.

64. But Hospira has refused to acknowledge the import of the holding in *Amgen v. Sandoz*. Instead, in correspondence dated August 19 and September 15, 2015, Hospira has taken the position that it is under no obligation to, and will not, provide *any* notice under § 262(*l*)(8)(A).

65. If Hospira is allowed to proceed based on its invalid notice of commercial marketing (or no notice at all), the 180-day period that the statute requires before commercial marketing may begin would run when the precise nature of the dispute between the parties, and even the need for litigation on certain patents, has not yet crystallized.

66. Hospira has indicated that it intends to violate the statute by categorically refusing to provide Amgen with a legally operative notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A). In serving a purported "notice of commercial marketing" before its biosimilar product is licensed, Hospira intends to deprive Amgen of the statutory time period for considering the need for and, if appropriate, seeking adjudication of, a potential preliminary injunction motion. Therefore, Hospira intends to continue violating this provision of the BPCIA absent an order of the Court compelling Hospira to comply.

67. Hospira's scheme to follow only those parts of the BPCIA it considers helpful to it, and to evade the parts it considers unhelpful to it, is unlawful and inequitable.

THE PATENTS-IN-SUIT

A. U.S. Patent No. 5,856,298

68. Amgen Inc. is the owner of all rights, title, and interest in U.S. Patent No. 5,856,298 ("the '298 Patent").

69. The '298 Patent is titled "Erythropoietin Isoforms." The '298 Patent was duly and legally issued on January 5, 1999 by the United States Patent and Trademark Office ("USPTO"). The inventor of the '298 Patent is Dr. Thomas Strickland, a former Amgen scientist. A true and correct copy of the '298 Patent is attached to this Complaint as Exhibit A.

70. AML is an exclusive licensee under the '298 Patent.

71. The ’298 Patent is directed to erythropoietin isoforms and erythropoietin compositions having specific numbers of attached sialic acid moieties, and methods for preparing the same.

B. U.S. Patent No. 5,756,349

72. Amgen Inc. is the owner of all rights, title, and interest in U.S. Patent No. 5,756,349 (“the ’349 Patent”).

73. The ’349 Patent is titled “Production of Erythropoietin.” The ’349 Patent was duly and legally issued on May 26, 1998 by the USPTO. The inventor of the ’349 Patent is Dr. Fu-Kuen Lin, a former Amgen scientist. A true and correct copy of the ’349 Patent is attached to this Complaint as Exhibit B.

74. AML is an exclusive licensee under the ’349 Patent.

75. The ’349 Patent is directed to vertebrate cells which are capable of producing recombinant human erythropoietin, and processes for producing recombinant erythropoietin using such cells.

CAUSES OF ACTION

FIRST COUNT
(DECLARATORY JUDGMENT THAT HOSPIRA’S REFUSAL TO GIVE LEGALLY EFFECTIVE NOTICE OF COMMERCIAL MARKETING VIOLATES 42 U.S.C. § 262(*l*)(8)(A))

76. Amgen incorporates by reference paragraphs 1-75 as if fully set forth herein.

77. This Count arises under 42 U.S.C. § 262 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) & 2202.

78. The BPCIA, 42 U.S.C. § 262(*l*), requires Hospira to follow mandatory procedures related to the filing of a BLA under 42 U.S.C. § 262(k).

79. Hospira has failed to comply with the mandatory requirements of the BPCIA. Hospira's violations of the BPCIA have injured Amgen, for example, by depriving Amgen of the procedural protections of the statute, by diminishing the value of Amgen's patents, and by subjecting Amgen to the burden of potentially unnecessary litigation.

80. To comply with 42 U.S.C. § 262(*l*)(8)(A), Hospira must provide notice to Amgen "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

81. Amgen received a letter from Hospira dated April 8, 2015, in which Hospira purported to provide notice of commercial marketing of the Hospira Epoetin Biosimilar Product, which the FDA has not yet approved for licensure. This purported notice is ineffective because, among other things, a biosimilar applicant may only give effective notice of commercial marketing after the FDA has licensed its product.

82. In later letters, Hospira has indicated that it does not intend to rely upon its April 8, 2015 notice.

83. Hospira has categorically represented to Amgen that it does not intend to provide Amgen with notice of commercial marketing after the FDA licenses the Hospira Epoetin Biosimilar Product and 180 days before commercial marketing of the Hospira Epoetin Biosimilar Product is to begin.

84. Hospira's refusal to provide Amgen with commercial notice after the FDA licenses the Hospira Epoetin Biosimilar Product and 180 days before commercial marketing of the Hospira Epoetin Biosimilar Product is to commence, is a violation of 42 U.S.C. § 262(*l*)(8)(A).

85. Amgen is entitled to a declaration of its rights under the statute and injunctive relief requiring Hospira to provide Amgen with legally effective notice of commercial marketing and for such further relief as may be appropriate in equity.

SECOND COUNT
(INFRINGEMENT OF U.S. PATENT NO. 5,856,298 UNDER 35 U.S.C. § 271(e)(2)(C))

86. Amgen incorporates by reference paragraphs 1-85 as if fully set forth herein.

87. Amgen is the owner of all rights, title, and interest in U.S. Patent No. 5,856,298 ("the '298 Patent").

88. Hospira seeks FDA approval under 42 U.S.C. § 262(k) to manufacture, use, offer to sell, or sell within the United States the Hospira Epoetin Biosimilar Product, a biosimilar version of Amgen's EPOGEN® (epoetin alfa) product.

89. Amgen included the '298 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

90. On information and belief (including Hospira's failure to state otherwise in its disclosures required by the BPCIA), Hospira intends to, and will, manufacture, use, offer to sell, or sell within the United States the Hospira Epoetin Biosimilar Product before the expiration of the '298 Patent.

91. On information and belief, Hospira has, intends to, and will immediately and imminently upon FDA licensure of the Hospira BLA, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Hospira Epoetin Biosimilar Product.

92. The submission of the Hospira BLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, or sale of the Hospira Epoetin Biosimilar

Product before the expiration of the ’298 Patent is an act of infringement of one or more claims of the ’298 Patent under 35 U.S.C. § 271(e)(2)(C).

93. Amgen will be irreparably harmed if Hospira is not enjoined from infringing one or more claims of the ’298 Patent. Amgen is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Hospira from any further infringement. Amgen does not have an adequate remedy at law.

94. Hospira’s commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, upon FDA approval of the Hospira Epoetin Biosimilar Product and before the expiration of the ’298 Patent will cause Amgen injury, entitling Amgen to damages or other monetary relief under 35 U.S.C. § 271(e)(4).

THIRD COUNT
(INFRINGEMENT OF THE ’298 PATENT UNDER 35 U.S.C. § 271(a))

95. Amgen incorporates by reference paragraphs 1-94 as if fully set forth herein.

96. Hospira seeks FDA approval under 42 U.S.C. § 262(k) to manufacture and sell the Hospira Epoetin Biosimilar Product, a biosimilar version of Amgen’s EPOGEN® (epoetin alfa) product.

97. On information and belief, Hospira has, intends to, and will immediately and imminently upon FDA licensure of the Hospira BLA, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Hospira Epoetin Biosimilar Product.

98. Hospira’s manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Hospira Epoetin Biosimilar Product before the expiration of the ’298 Patent, will infringe one or more claims of the ’298 Patent under 35 U.S.C. § 271(a).

99. An actual controversy has arisen and now exists between the parties concerning whether the Hospira Epoetin Biosimilar Product has or will infringe one or more claims of the ’298 Patent.

100. Amgen is entitled to a judgment that Hospira has or will infringe one or more claims of the ’298 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, the Hospira Epoetin Biosimilar Product before the expiration of the ’298 Patent.

101. Amgen is entitled to injunctive relief prohibiting Hospira from making, using, offering to sell, or selling within the United States, or importing into the United States, the Hospira Epoetin Biosimilar Product before the expiration of the ’298 Patent. Amgen does not have an adequate remedy at law.

102. Hospira’s manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Hospira Epoetin Biosimilar Product before the expiration of the ’298 Patent will cause Amgen injury, entitling Amgen to damages under 35 U.S.C. § 284.

FOURTH COUNT
(INFRINGEMENT OF U.S. PATENT NO. 5,756,349 UNDER 35 U.S.C. § 271(a))

103. Amgen incorporates by reference paragraphs 1-102 as if fully set forth herein.

104. On information and belief, Hospira infringed one or more claims of the ’349 Patent under 35 U.S.C. § 271(a) by engaging in the manufacture or use of the vertebrate cells claimed in the ’349 patent before the expiration of the ’349 Patent.

105. Hospira’s infringement of one or more claims of the ’349 Patent before the expiration of the ’349 Patent entitles Amgen to damages under 35 U.S.C. § 284.

106. Hospira's infringement of one or more claims of the '349 Patent before the expiration of the '349 Patent entitles Amgen to an injunction prohibiting Hospira from exporting, using, offering for sale, or selling any infringing vertebrate cells produced or used before the expiration of the '349 patent, and from exporting, using, offering for sale, or selling any Hospira Epoetin Biosimilar Product manufactured by an infringing process prior to the expiry of the '349 patent. Amgen does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Amgen respectfully requests that this Court enter judgment in its favor against Hospira and grant the following relief:

A. An order enjoining Hospira from commercially marketing the Hospira Epoetin Biosimilar Product until Amgen is restored to the position it would have been in had Hospira met its obligations under the BPCIA;

B. An order enjoining Hospira from continuing to seek FDA review of its § 262(k) application and/or compelling Hospira to suspend FDA review of its § 262(k) application until Hospira has obtained permission from Amgen to use the EPOGEN® (epoetin alfa) license or Hospira has restored to Amgen the benefits afforded to Reference Product Sponsors in the BPCIA;

C. A declaration that the notice of commercial marketing that Hospira provided on April 9, 2015 is ineffective under 42 U.S.C. § 262(*l*)(8)(A);

D. A declaration of Amgen's rights under 42 U.S.C. § 262(*l*)(8)(A);

E. An injunction requiring Hospira to provide Amgen, on or after FDA licensure of the Hospira Epoetin Biosimilar Product, notice of the date of the first commercial marketing of the Hospira Epoetin Biosimilar Product thereby complying with 42 U.S.C. § 262(*l*)(8)(A) and prohibiting Hospira from commencing first commercial marketing of the licensed Hospira

Epoetin Biosimilar Product until a date that is 180 days after Hospira provides this notice to Amgen;

F. A judgment that Hospira has infringed one or more claims of the ’298 Patent under 35 U.S.C. § 271(e)(2)(C)(i), by submitting to the FDA BLA No. 125545 to obtain approval of the Hospira Epoetin Biological Product under the Public Health Service Act to engage in the commercial manufacture, use, or sale of the Hospira Epoetin Biosimilar Product before the expiration of a patent that claims the product or use of the product;

G. A judgment that Hospira has or will infringe one or more claims of the ’298 Patent by engaging in the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Hospira Epoetin Biosimilar Product before the expiration of the ’298 Patent;

H. A judgment that Hospira has infringed one or more claims of the ’349 Patent by engaging in the manufacture or use of the vertebrate cells claimed in the ’349 patent before the expiration of the ’349 Patent and by engaging in a process claimed in the ’349 patent to produce Hospira Epoetin Biosimilar Product before the expiration of the ’349 patent;

I. An order enjoining Hospira, its officers, partners, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in active concert or participation with any of them from infringing the ’298 Patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any current or future versions of the Hospira Epoetin Biosimilar Product;

J. An order enjoining Hospira, its officers, partners, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in

active concert or participation with any of them from exporting, using, offering for sale, or selling any infringing vertebrate cells produced or used before the expiration of the '349 patent, and from exporting, using, offering for sale, or selling any Hospira Epoetin Biosimilar Product manufactured by an infringing process before the expiration of the '349 patent;

K. A judgment compelling Hospira to pay to Amgen damages or other monetary relief adequate to compensate for Hospira's infringement, in accordance with 35 U.S.C. § 271(e)(4)(C) and § 284;

L. A declaration that this is an exceptional case and awarding to Amgen its attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

M. Such other relief as this Court may deem just and proper.

DEMAND FOR A JURY TRIAL

Amgen hereby demands a jury trial on all issues so triable.

OF COUNSEL:

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Amanda K. Antons
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Wendy A. Whiteford
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November 6, 2015

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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mnoreika@mnat.com

Attorneys for Amgen Inc. and Amgen Manufacturing, Limited

CERTIFICATE OF SERVICE

I hereby certify that on November 6, 2015, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 6, 2015, upon the following in the manner indicated:

Dominick T. Gattuso, Esquire — *VIA ELECTRONIC MAIL*
PROCTOR HEYMAN ENERIO LLP
300 Delaware Avenue
Suite 200
Wilmington, DE 19801
Attorneys for Defendant Hospira, Inc.

Thomas J. Meloro, Esquire — *VIA ELECTRONIC MAIL*
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, NY 10019-6099
Attorneys for Defendant Hospira, Inc.

/s/ Jack B. Blumenfeld
Jack B. Blumenfeld (#1014)

EXHIBIT B

MARSHALL GERSTEIN BORUN LLP
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KEVIN M. FLOWERS, PH.D.
PARTNER
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kflowers@marshallip.com

March 31, 2015

VIA E-MAIL

Thomas J. Meloro
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, New York 10019
tmeloro@willkie.com

Re: Hospira, Inc. Abbreviated Biologic License Application
42 U.S.C. § 262(l)(2) disclosures

Mr. Meloro:

Under 42 U.S.C. § 262(l)(2)(A), Hospira is required to produce to Amgen a copy of its ABLA and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." After reviewing the version of the ABLA that you produced to us, we have discovered that it does not fully "describe the process or processes used to manufacture the biological product that is the subject of" the application. [redacted]

Should you have any questions or concerns regarding this matter, please do not hesitate to contact me by phone or e-mail.

Sincerely,

Marshall, Gerstein & Borun, LLP

Kevin M. Flowers

EXHIBIT C

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PARTNER
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kflowers@marshallip.com

April 27, 2015

VIA E-MAIL

Michael W. Johnson
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, New York 10019
mjohnson1@willkie.com

Re: Hospira, Inc. Abbreviated Biologic License Application

Mr. Johnson:

I write in response to your letter of April 21, 2015.

By refusing to produce the manufacturing information identified in my March 31, 2015 letter to Thomas Meloro, Hospira has not complied with 42 U.S.C. § 262(l)(2)(A), which requires Hospira to produce "such other information that describes the process or processes used to manufacture the biological product that is the subject" of Hospira's abbreviated biologic license application. Hospira's refusal to produce this manufacturing information will make it impossible for Amgen to assess whether a claim for patent infringement could reasonably be asserted against Hospira with respect to certain of Amgen's patents. For example, Amgen owns a number of patents that claim processes for culturing cells used in manufacturing biological products. Without the complete manufacturing information that Hospira is required to produce, Amgen cannot assess the reasonableness of asserting claims for infringement of these patents based on Hospira's actual manufacture of its epoetin product.

In your letter, you request that Amgen identify "any specific patents for which Amgen believes it may require additional information in order to assess whether a claim of infringement can be made," and "Hospira will determine if there is additional information" that it can provide. This proposal is inconsistent with the process dictated by §§ 262(l)(2)–(5), which call for Hospira to produce its application and manufacturing information to Amgen and Amgen to respond with a list of patents for which it believes it could reasonably assert a claim of patent infringement if Hospira engaged in the making, using, offering to sell, selling, or importing into the United States the biological product that is the subject of Hospira's application. The statute

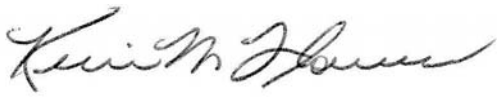
does not call for Amgen to provide a list of potentially relevant patents for Hospira to consider in deciding whether or not to disclose manufacturing information called for by § 262(l)(2)(A).

In any event, contrary to your assertion that Amgen will be "prohibited from asserting a claim of infringement against Hospira's ABLA product on any patent that is not included" on Amgen's § 262(l)(3)(A) disclosure, no such limitation can apply here with respect to patents for which Amgen was prohibited from forming a belief as to the reasonableness, or not, of asserting a claim for patent infringement by Hospira's refusal to disclose manufacturing information when such disclosure is expressly required under § 262(l)(2)(A).

Should you have any questions or concerns regarding this matter, please do not hesitate to contact me by phone or e-mail.

Sincerely,

Marshall, Gerstein & Borun LLP



Kevin M. Flowers

EXHIBIT D

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KEVIN M. FLOWERS, PH.D.
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May 1, 2015

Via E-Mail

Michael W. Johnson
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, New York 10019
mjohnson1@willkie.com

Re: Hospira, Inc.'s Biological License Application No. 125545

Mr. Johnson:

I write in response to your April 30, 2015 letter. We are surprised to learn that Hospira now contends that the manufacturing information identified in my March 31, 2015 letter is contained in the BLA that Hospira has produced to us. In your April 21 letter, you argued that Hospira is not obligated to produce the information identified in my March 31 letter. You further requested a list of specific patents so that Hospira could "determine if there is additional information" that it could provide. But you did not contend that this information appears in Hospira's BLA. If Hospira now contends that the manufacturing information identified in my March 31, 2015 letter is included in the BLA that Hospira has produced to us, please identify the pages of Hospira's BLA where you contend that this additional information appears.

[redacted]

Finally, we find your suggestion that Amgen is attempting to "manufacture a controversy" to be counterproductive. By identifying manufacturing information that Hospira has not produced under 42 U.S.C. § 262(l)(2)(A), Amgen is attempting to comply with its

obligations under that statute. To the extent that Hospira does not agree to produce this information, the disagreement between the parties is real, not "manufactured."

Should you have any questions or concerns regarding this matter, please do not hesitate to contact me by phone or e-mail.

Sincerely,

Marshall, Gerstein & Borun LLP

Kevin M. Flowers

EXHIBIT E

WILLKIE FARR & GALLAGHER LLP

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787 Seventh Avenue
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April 21, 2015

Kevin M. Flowers, PH.D.
Marshall, Gerstein & Borun, LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357

Re: Hospira, Inc. Abbreviated Biologic License Application

Dear Mr. Flowers:

I am writing in response to your March 31, 2015 letter regarding Amgen's request for additional information concerning certain raw materials described in Hospira's ABLA.

Hospira has provided to Amgen a complete copy of its ABLA, which more than adequately describes the processes used to manufacture its biological product. Amgen's desire for additional

[redacted]

Pursuant to 35 U.S.C. § 271(e)(6)(C), Hospira reminds Amgen that it is prohibited from asserting a claim of infringement against Hospira's ABLA product on any patent that is not included in a timely manner on Amgen's list of patents provided pursuant to 42 U.S.C. § 262 (*l*)(3)(A).

Sincerely,

Michael W. Johnson

EXHIBIT F

WILLKIE FARR & GALLAGHER LLP

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Fax: 212 728 8111

April 30, 2015

Kevin M. Flowers, PH.D.
Marshall, Gerstein & Borun, LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357

Re: Hospira, Inc. Abbreviated Biologic License Application

Dear Mr. Flowers:

I am writing in response to your April 27, 2015 letter. Contrary to your assertions, Hospira has complied with its obligations under 42 U.S.C. § 262 (*l*)(2)(A). Hospira has provided a complete copy of its ABLA, which contains "information that describes the process or processes used to manufacture the biological product that is the subject of such application," including information related to the raw materials referenced in your previous letter.

Amgen has had a full and fair opportunity to evaluate Hospira's application, including information describing the process used to make the product of the application. Hospira looks forward to receipt of Amgen's list of patents pursuant to 42 U.S.C. § 262 (*l*)(3)(A), and notes that the provisions of 35 U.S.C. § 271(e)(6)(C) will apply with full force concerning Hospira's application. Despite your attempts to manufacture a controversy regarding the sufficiency of the information disclosed by Hospira, none exists here, and Hospira will seek to preclude Amgen from asserting any patent that is not included on your (3)(A) list.

Sincerely,

Michael W. Johnson

EXHIBIT G

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Originally Filed: May 2, 2016
Redacted Version Filed: May 9, 2016
REDACTED - PUBLIC VERSION

The Honorable Richard G. Andrews
United States District Judge
For the District of Delaware
844 N. King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Amgen Inc. v. Hospira, Inc.*
C.A. No. 15-839-RGA

Dear Judge Andrews:

We write on behalf of plaintiffs Amgen Inc. and Amgen Manufacturing, Limited seeking an order to compel defendant Hospira, Inc. to produce two categories of documents and information: manufacturing information and FDA communications. These discovery deficiencies are scheduled to be addressed at the May 4 discovery conference.

I. The Court should order Hospira to produce the requested manufacturing information

Hospira has refused to produce complete information regarding the composition of the cell-culture medium it uses to manufacture the biological product at issue in this case (information which Hospira's counsel characterized to the Court as mere "scraps of paper"). This specific information would allow Amgen to determine whether Hospira's manufacturing process infringes Amgen's cell-culture patents. During the information exchange under the Biologics Price Competition and Innovation Act ("the BPCIA"), Hospira was required to provide to Amgen "information that describes the process or processes used to manufacture the biological product that is the subject" of Hospira's abbreviated Biologics License Application ("aBLA") to satisfy its disclosure obligation under 42 U.S.C. § 262(*l*)(2)(A). The Federal Circuit has held that if a biosimilar applicant refuses to provide this "required information" during the BPCIA exchange, the reference product sponsor can commence a patent infringement suit and "access the required information through discovery." *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 (Fed. Cir. 2015). If Hospira is permitted to withhold information expressly called for by § 262(*l*)(2)(A) in the BPCIA pre-suit process, and then refuse to provide discovery of that withheld information in this subsequent suit, Hospira could evade detection of patent infringement and thereby deny Amgen access to the courts to protect its patent rights. This would be the very antithesis of Congress's goals in enacting the BPCIA: establishing an abbreviated pathway for regulatory approval of biologics that also preserves the incentives of the patent

system. Accordingly, Hospira should be ordered to immediately produce the requested information to Amgen.

A. Hospira has refused to produce complete manufacturing information

After reviewing Hospira's aBLA during the BPCIA's information exchange, and finding that it did not contain complete information regarding the composition of the cell-culture medium Hospira uses to manufacture its product, Amgen requested that Hospira provide this information because it relates to "the process or processes used to manufacture the biological product that is the subject" of Hospira's aBLA, information that is required to be provided under § 262(*l*)(2)(A). (Exhs. 1-3.) Hospira refused to provide the information. (Exhs. 4-5.) Amgen informed Hospira that without this specific manufacturing information, Amgen could not determine whether 42 U.S.C. § 262(*l*)(3)(A) allowed Amgen to include its cell-culture patents on its § 262(*l*)(3)(A) patent list, to provide the detailed statement required under § 262(*l*)(3)(C), or to engage in the dispute-resolution negotiations with respect to these patents or include these patents in an immediate patent-infringement suit, as contemplated by §§ 262(*l*)(4)-(6). (Exhs. 1-3.)

After initiating this litigation, Amgen served Hospira with Interrogatory No. 1 and Request for Production Nos. 13-20 specifically seeking this information. Hospira again refused to provide the information. (Exh. 6 at 4-6; Exh. 7 at 14-21.) Amgen attempted to resolve this dispute informally by letter (Exh. 8) and on a meet-and-confer teleconference. For a third time, Hospira refused to produce the requested information.

B. Under *Amgen v. Sandoz*, Amgen "can access the required information through discovery"

In *Amgen*, the Federal Circuit repeatedly referred to the information described in § 262(*l*)(2)(A) as "required information." 794 F.3d at 1355-56. The Federal Circuit held that when a biosimilar applicant refuses to provide this required information during the BPCIA information exchange, a reference product sponsor may bring a patent-infringement suit and "access the required information through discovery." *Id*. at 1356. Otherwise, the applicant could "unlawfully evade[] the detection of process patent infringement" by refusing to provide the required information. *Id.* at 1355. In *Amgen*, after Sandoz initially refused to disclose the information required by § 262(*l*)(2)(A) during the information exchange, Amgen sued Sandoz for infringement of a method-of-treatment patent. *Id.* at 1353. Sandoz then produced its information in discovery. *Id.* ("[T]he sponsor may file an infringement suit under paragraph (*l*)(9)(C) and obtain the information in discovery, which Amgen has done."). The information Sandoz produced in discovery was not limited to information relevant to infringement of Amgen's method-of-treatment patent.

Under Hospira's reasoning, a biosimilar applicant could withhold all "required information" under § 262(*l*)(2)(A) forever, preventing a reference product sponsor from *ever* assessing the infringement of its full portfolio of patents. That cannot be correct; the very purpose of § 262(*l*) is the identification and resolution of patent disputes through an exchange of information, negotiation, and only if necessary, litigation. The Court should order Hospira to immediately produce this "required information."

C. Ordering production would further a goal of the BPCIA

The BPCIA "ensure[s] that litigation surrounding relevant patents will be resolved expeditiously and *prior to the launch* of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." *Amgen*, 794 F.3d at 1363

(Newman, J., concurring) (quoting *Biologics and Biosimilars*, 111th Cong. 9 (July 14, 2009) (statement of Rep. Eshoo)). Through § 262(*l*)(2)(A), the BPCIA requires the applicant to provide, in addition to its aBLA, "information that describes the process or processes used to manufacture the biological product that is the subject of such application." This ensures that the reference product sponsor, here Amgen, has the facts to assess whether it "believes a claim of patent infringement could reasonably be asserted . . . , if a person . . . engaged in ***the making*** . . . of the biological product." 42 U.S.C. § 262(*l*)(3)(A) (emphasis added.) Thus, in contrast to the Hatch-Waxman Act, which deals with patent disputes only over patents on the chemical entity or methods of use, the BPCIA includes manufacturing patents, which can be especially important in protecting innovation in the area of biologics. Without disclosure or discovery of manufacturing information, the reference product sponsor might not be able to determine which of its manufacturing patents are infringed by the applicant's manufacturing process. The Federal Circuit acknowledged this concern that an applicant could otherwise "evade[] the detection of process patent infringement." *Amgen*, 794 F.3d at 1355. By refusing to provide the requested information, Hospira is preventing the parties from resolving potential disputes over other relevant manufacturing patents.

D. Production would pose little or no burden on Hospira

Hospira's counsel admitted that Hospira's production of the requested manufacturing information would not be unduly burdensome, referring to it as "other scraps of paper." (Exh. 9 (2/16/16 Oral Arg. Trans.) at 26:8.) The requested production is certainly "proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1).

II. The Court should order Hospira to produce communications with the FDA

Hospira has also refused to produce all of its communications with the FDA regarding the aBLA and its related Investigational New Drug Application ("the IND"). Amgen has requested this information in Request for Production Nos. 1-5 and 7-10. In Hatch-Waxman litigation, all communications with the FDA are routinely produced so that the parties and the court are aware of events that may impact the ongoing litigation. These communications are relevant here, as they will reveal the progress of the FDA's review and timeline for potential approval of Hospira's aBLA, and the substance and significance of any amendments to the aBLA or IND, which may relate to, for example, changes to manufacturing processes, manufacturing sites, or the structure or composition of the product. Amendments or supplements to the aBLA or IND could reveal infringement of additional Amgen patents, as contemplated by 42 U.S.C. § 262(*l*)(7), or on the other hand, evidence the presence or absence of a defense or remedy. Based on public information, Hospira has received a "complete response letter" from the FDA (essentially a summary of the FDA's views about what needs to be addressed before Hospira's aBLA could be approved). Consequently, the information in the copy of the aBLA provided to Amgen last year may be incomplete or outdated. The communications with the FDA that Hospira is willing to produce in response to Amgen's requests—only regarding the cells used to manufacture its drug substance, or the isoforms in its drug product—are insufficient given the context and nature of this case. (Exh. 7 at 5-13.) Hospira must produce all of its communications with the FDA so that Amgen and the Court can have a full understanding of Hospira's product and its manufacturing processes, the status of its licensure, and potential defenses and remedies in this case.

The Court should order Hospira to produce, on an ongoing basis, all of its communications with the FDA regarding its aBLA and IND.

Respectfully,

/s/ Maryellen Noreika

Maryellen Noreika (#3208)

MN/dlw
Enclosures
cc: Clerk of Court (Via Hand Delivery; w/ encl.)
All Counsel of Record (Via Electronic Mail; w/ encl.)

CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of July, 2016, I caused the foregoing Opposition to Hospira, Inc.'s Motion to Dismiss Appeal for Lack of Jurisdiction to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the Court's CM/ECF system.

The following counsel of record were served electronically via the Court's CM/ECF system and via electronic mail:

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